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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,506	12/21/2001	Hanuman B. Jampani	ETH-1601 (J&J 3.0-071)	4582

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	S

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/029,506	JAMPANI ET AL.
	Examiner	Art Unit
	Blessing M. Fubara	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 April 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24,26-39 and 43-45 is/are rejected.
- 7) Claim(s) 25 and 40-42 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 December 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of election with traverse filed 04/28/03. The election requirement is however withdrawn in light of the arguments presented in paper number 4.

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Applicants are respectfully requested to submit an IDS if it is the applicants' intention.

Specification

Applicants under "description of the preferred embodiments" described elements about the figures that are not denoted on the figures as filed. For example, on line 1 page 6, delivery means 110 in figure 2 is described and there is no 110 shown in figure 2, also, in line 10, bioactive agent 114 14 is disclosed to be shown in figure 2 and there is no showing of 114 14 in figure 2. Similarly, there is no 210 and 212 14 and 232 in figure 3, there is however 2321 in figure 3 (see page 6, lines 20 and 22 of the instant specification). Also figure 4 does not have delivery mean 310 as disclosed in line 32 of page 6 of the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11, 17-24, 26-33, 39, 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal et al. (EP 0 562 864).

Rosenthal discloses a wound dressing material or implant material that comprises a matrix of bioabsorbable biopolymer material and a substructure of bioabsorbable biopolymer films which is embedded in the matrix structure and where one or more active agents are incorporated separately into the matrix and/or the substructure in order to provide controlled or phasic release of the active agent into the wounds (abstract and column 3, lines 22-34).

Rosenthal teaches that polyglycolic acid, structural proteins such as collagen, elastin and fibronectin and polysaccharides are bioabsorbable materials that are used to fabricate the porous wound dressing or implants (column 1, lines 6-22). Anti-microbial is an example of active agent incorporated to control infection in the heteromorphic wound dressing sponge of Rosenthal (column 3, lines 36 and 37). In example 3, a two-component heteromorphic sponge wound dressing comprising chlorhexidine gluconate in both the sponge matrix and the substructure is prepared and in this case, a variation of the preparatory method calls for the use of oxidized regenerated cellulose fabric precoated with hyaluronic acid (column 7, line 56 to column 8 line 6).

In Rosenthal, the substructure of polyglycolic acid film is the enclosing film and since the anionic carrier of oxidized regenerated cellulose interacts with the active anti-microbial agent that satisfies the limitation of cationic agent, the interaction would inherently be ionic. The instant method is directed to administering a pharmaceutical active agent and the reference applies the wound dressing sponge to a wound and the rate would inherently depend on the rate of biodegradability of the substructure. Thus the teachings of Rosenthal meet the limitation of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12-16 and 34-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. (EP 0 562 864).

Rosenthal clearly teaches the porous biocompatible device of the instant invention except that Rosenthal fails to give the size of the pores. However, the pores should have certain sizes and since Rosenthal is silent on the size of the pore, it would appear that the prior art teaches all pore sizes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous wound dressing sponge according to the teaching of Rosenthal. One having ordinary skill in the art would have been motivated to prepare the porous wound dressing sponge having pore sizes that would permit the effective release of the

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anti-microbial agent. There is no showing demonstrating that the pore sizes recited in the instant claims provide unusual results.

6. Claims 25 and 40-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a polymer film substructure that is made of polyethylene, polypropylene or mixtures thereof; in the prior art, the wound dressing sponge does not contain additional carrier.

Observation:

Claim 3 "...means for delivery of claim 2." It appears that the claim may be clearer if it reads
...means for delivery according to claim 2...

Claims 7, 21 and 31, ---is--- is missing after "carrier" in lines 2

Claim 12, "of has" may be having

Claim 39, line 3, after "PLG" a comma or and is missing

Claim 44, line 3, the second "of" may be an ---a---

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
July 12, 2003

Blessing Fubara